K07 1384

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510(k) Summary
as required by 807.92

1. Company Identification

NIHON SEIMITSU SOKKI CO., LTD. (Nissei)
2508-13 Nakago, Shibukawa, Gunma 377-0293 Japan
Tel: +81-279-20-2311
Fax: +81-279-20-2411

OCT - 9 2007

2. Official Correspondent

Hideki Tomaru (Mr.)
Assistant Manager of International Sales Div.

3. Date of Submission

May 16, 2007

4. Device Trade name

Model DS-1901 Digital Blood Pressure Monitor

5. Common/Usual Name

Blood Pressure Monitor

6. Classification Number

Class II, 74 DXN, 21 CFR 870. 1130 – Cardiovascular Devices Panel

7. Predicate Device

Manufacturer	:	Nihon Seimitsu Sokki, Co., Ltd. (Nissei)
Trade Name	:	Model 1901 Digital Blood Pressure Monitor
510(k) No.	:	K050697

8. Description of Device

The Model DS-1901 Digital Blood Pressure Monitor is an automatic sphygmomanometer intended for measurement, including self-measurement by the patient, of systolic and diastolic blood pressure and pulse rate in adult patients in a homecare environment. Blood pressure is measured in the brachial artery using an arm cuff of the appropriate size. The unit includes an air pump for automatic cuff inflation, an electric valve, pushbutton controls, circuitry to detect and process minute pressure oscillations, an LCD display of systolic and diastolic blood pressure readings, pulse rate and irregular pulse rhythm a wide-ranged arm cuff and a carrying case. The memory circuit stores the thirty most recent readings plus the computed average of the stored readings, which will be retained after power turn-off or battery removal and can be intentionally deleted. The system is powered by four AA-size batteries or, optionally, by a 6V AC adapter.

9. Indication for use

The DS-1901 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adult patients, i.e., age 12 and above. The product is recommended for use by patients with labile blood pressure or known hypertension in a home care environment as an adjunct to medical management.

The device displays irregular pulse rhythm indication when it is detected during measurement.

10. Technical Characteristics

There is not a difference of intended use and technology characteristic between the subject device and any predicate device (K050697). The reason for 510(k) submission is to include detection and display of irregular pulse rhythm in the Indication for use Statement. This feature is already included in the predicate device. Comparison table of the principal characteristics of 2 devices in Attachment 1 shows that new and predicate devices are equivalent in the areas of technical characteristics, general functions.

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Appendix 1: Comparison Table with Predicate Device

SUBJECT DEVICE	PREDICATE DEVICE:K050697
Indications for use: Measurement of blood pressure and pulse rate adult patients Function to detect and display irregular pulse wave	***Indications for use:*** Measurement of blood pressure and pulse rate adult patients
Method of measurement: It is the same as the right	***Method of measurement:*** Oscillometric
Display of indications: It is the same as the right	***Display of indications:*** 12-digit LCD: systolic, diastolic, pulse rate, memory data number, 4 status clock – hour and minute
Error Indications: It is the same as the right	***Error Indications:*** Four, pluse weak battery charge on statsu indicator
Range of pressure: It is the same as the right	***Range of pressure:*** 0 to 300 mmHg
Range of measuring: It is the same as the right	***Range of measuring:*** Systolic: 50 to 250 mmHg Diastolic: 40 to 160 mmHg Pulse rate: 40 to 160 bpm
Accuracy of measurement: It is the same as the right	***Accuracy of measurement:*** Pressure:+/- 3 mmHg Pulse rate: +/- 5% or reading
Memory: It is the same as the right	***Memory:*** 30 most recent systolic and diastolic Reading plus average measured time
Inflation: It is the same as the right	***Inflation:*** Automatic by air pump
Deflation: It is the same as the right	***Deflation:*** None
Exhaust: It is the same as the right	***Exhaust:*** Automatic by EV
Operating Temperature and Humidity: It is the same as the right	***Operating Temperature and Humidity:*** +10℃ to 40℃; 15 to 90% RH
Storage Temperature: It is the same as the right	***Storage Temperature:*** -20℃ to +50℃; 15 to 90% RH
Cuff Size: It is the same as the right	***Cuff Size:*** 142mm×580mm (arm circumference range 230 to 460mm)
Power: It is the same as the right	***Power:*** 4×1.5-volt "AA" batteries, or 6VDC AC adaptor, consumption 4.0 W (max.)
Weight. Main unit: It is the same as the right	***Weight. Main unit:*** Approx. 330 grams

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2007

Nihon Seimitsu Sokki Co. Ltd.
c/o Mr. Koji Kubo
Cosmos Corporation
3F, 2-17-6 Akebono-cho
Tachikawa-shi, Tokyo 190-0012
JAPAN

Re: K071384
Trade/Device Name: Digital Blood Pressure Monitor, Model DS-1901
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 11, 2007
Received: September 13, 2007

Dear Mr. Kubo:

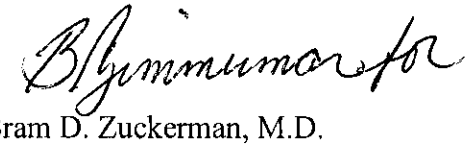
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Y/1

510(K) Number: K071384

Device Name: Model DS-1901 Digital Blood Pressure Monitor

Indications for Use:

The DS-1901 system is intended for the noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate in adult patients, i.e., age 12 and above. The product is recommended for use by patients with labile blood pressure or known hypertension in a home care environment as an adjunct to medical management.

The device displays irregular pulse rhythm indication when it is detected during measurement.

Prescription Use_____ AND / OR Over-The-Counter Use ____X____

(Per 21 CFR 801.109 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071384